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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,662	04/27/2001	Eva Raschke	8325-0012	9004

7590            04/07/2004

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EXAMINER
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SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/844,662	RASCHKE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 March 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3, 6-18, 20-24, 27 and 57-86 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-3, 6-18, 20-24, 27, and 57-86 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ .  |

## DETAILED ACTION

Two preliminary amendments to the claims have been entered in this Application. The first was received and entered, on 5/23/03. Due to difficulty in obtaining entry of this amendment, Applicant sent an identical amendment which was entered on 6/26/03.

Claims 4, 5, 19, 25, 26, and 28-56 were canceled, and claims 57-86 were added.

Claims 1-3, 6-18, 20-24, 27, and 57-86 are pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 6, 7, 9-11, 20-24, 27, 79-81, and 83, drawn to methods for binding to a binding site in cellular chromatin an exogenous protein classified in class 514 subclass 2.
2. Claims 75 and 76, drawn to methods for binding to a binding site in cellular chromatin an exogenous nucleic acid by introducing into a cell said nucleic acid classified in class 514 subclass 44.
3. Claim 78 drawn to drawn to a method for binding to a binding site in cellular chromatin an exogenous small molecule therapeutic, that is not a protein or a nucleic acid, by introducing into a cell said exogenous small molecule therapeutic, classified in class 514 subclass 1.
4. Claims 58 and 59, drawn to a complex between an exogenous nucleic acid and a binding site in cellular chromatin, classified in class 514, subclass 24.5.

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5. Claim 61, drawn to a complex between an exogenous small molecule therapeutic and a binding site in cellular chromatin, wherein the small molecule is not a protein or nucleic acid, classified in class 514, subclass 2.
6. Claims 62-64, 67 and 68, drawn to a complex between an exogenous protein and a binding site in cellular chromatin, classified in class 530, subclass 358.

Claims 1-3, 12-18, 72-74, 77, 82, and 84-86 link(s) inventions 1-3. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 12-18, 72-74, 77, 82, and 84-86.

Claims 57, 60, 65, 66, 69-71 link inventions 4-6. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 57, 60, 65, 66, 69-71.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Should Applicant elect group 1, a further group restriction between the following inventions is required:

Invention 1a, claims 6, 7, 9-17, 20-24, 27, and 79-81, drawn to methods of binding to a binding site binding in cellular chromatin an exogenous protein by introducing into a cell said protein, classified in class 514, subclass 2,

And

Invention 1b, claims 11-17, 20, and 83, drawn to methods for binding to a binding site binding in cellular chromatin an exogenous protein by introducing into a cell a nucleic acid that expresses the protein, classified in class 514 , subclass 44.

This further requirement is not an election of species, it is a restriction requirement between independent and distinct inventions. Applicant will be entitled to examination of both inventions 1a and 1b only if linking claims 1-3, 12-18, 72-74, 77, 82, and 84-86 are found to be allowable.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because they rely upon different exogenous molecules, i.e. proteins, nucleic acids, or non-protein, non-nucleic acid small molecule therapeutics, that rely upon different or unknown binding interactions to exert their effects. Further, these molecules are not disclosed as capable of use together.

Inventions 4-6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are composed of different molecules, i.e. proteins, nucleic acids, or non-protein-non-nucleic acid small molecule therapeutics, that have unrelated or unknown structures and are not disclosed as capable of use together.

Inventions 1-3 and 4-6 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compositions of inventions 4-6 can be isolated from naturally occurring cells, i.e. from cells in which transcription factors are bound to a binding site, from cell undergoing replication or DNA repair in which nucleic acid primers are bound to a binding site, or cells in which a naturally occurring small molecule therapeutic such as bleomycin is bound to a binding site.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN  
PRIMARY EXAMINER  
  
DR